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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,923	11/28/2001	William R. Law	21726/92990	7447

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EXAMINER

CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 01/05/2005

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/994,923

Applicant(s)

LAW, WILLIAM R.

Examiner

L. E. Crane

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/6, 17 & 12/17/02; 01/02/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152:

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/6/02, 9/17/02</u> | 6) <input type="checkbox"/> Other: _____ |

The previous suggestion that any of the instant claims are allowable has been withdrawn. The following Office action is a new non-final rejection.

Claim 16 has been cancelled, no new claims have been added, claims 5, 6 and 15 have been amended, and the disclosure has been amended as per the amendment filed December 17, 2002. Two Information Disclosure Statements (2 IDSs) filed September 6 and September 17, 2002 have been received with all cited reference and made of record. Also a Terminal Disclaimer has been received, reviewed and made of record.

Claims 1-15 remain in the case.

The disclosure is objected to because of the following informalities:

The drawings received September 17, 2002 have been reviewed by a draftsman and by instant Examiner. The newly submitted Figures continue to be deficient as noted by the draftsman on the attached PTO-948. The chemical structures presented in individual figures may be incorporated into the specification as well (see the '084 and '432 patent documents as examples). However, the chemical structure in Figure 12 defined in the disclosure as representing "ARADS" includes variables "R" and "n" which have not been defined, thereby rendering the disclosure incomplete.

Appropriate correction is required.

Applicant's arguments filed December 17, 2002 have been fully considered but they are not deemed to be persuasive.

Applicant may elect to incorporate portions of the Pragnacharyulu reference (PTO-1449 ref. A.21) according to *Hawkins et al.* See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCAP 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). In each of these cases, the incorporations are of the complete document, and each fails to properly point out the particular portions of the US patent(s) being incorporated. See also MPEP §608.01(p)(1)(A) noting *In re de Seversky* and in the same paragraph (column 2 of p. 600-769, August 2001 edition) the instruction which reads as follows: "[p]articular attention should be directed to specific portions of the referenced document wherein the subject matter being incorporated may be found."

35 U.S.C. §101 reads as follows:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

Claim 15 is rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App., 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149, 149 USPQ 475 (D.D.C. 1966).

Examiner suggests that the term “used” in claim 15 may be replaced by the term -- administered -- or the like as one way to avoid the instant rejection.

Applicant’s arguments filed December 17, 2002 have been fully considered but they are not deemed to be persuasive.

Applicant has failed to respond to this grounds of rejection.

Claims 1-3 and 6-15 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 6 the term “ARADS” is incomplete for failure of the disclosure and figures to provide a completely defined chemical name. Applicant is referred to the objection supra concerning the acronym “ARADS” as found in Figure 12 and that the generic chemical name now found in claim 6 appears to be incorrect; the included term “arylakan-2-ols” is apparently intended to read -- arylalkan-2-ols --.

Applicant’s arguments with respect to claims 1-15 have been considered but are deemed to be moot in view of the new grounds of rejection.

Claims 1-3 and 7-15 are incomplete because each of said claims fails to include a non-functional definition of the active ingredient or ingredients being claimed.

Applicant’s arguments with respect to claims 1-15 have been considered but are deemed to be moot in view of the new grounds of rejection.

The contents of claim 15 between the terms "composition" and "comprising" (i.e. the preamble) is entirely superfluous because a pharmaceutical composition claim only has patentable weight courtesy of its definition(s) of the active ingredient(s), the carrier(s), and the relative proportions thereof. Deletion is respectfully requested.

Applicant's arguments with respect to claims 1-15 have been considered but are deemed to be moot in view of the new grounds of rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claim 15 is rejected under 35 U.S.C. §102(b) as being anticipated by **Ryder et al. '785** (PTO-892 ref. E).

Applicant is referred to the '785 patent at columns 13-15 wherein several "PHARMACEUTICAL COMPOSITIONS" of pentostatin are specifically disclosed. Applicant is respectfully requested to note that the preamble noted in a rejection above is not a proper basis for establishing patentable distinction over the noted prior art for the reason given in the rejection supra.

Assuming that the noted claim was intended to be directed solely to pharmaceutical compositions of ADA inhibitors known in the art, the same grounds applied above are also deemed to apply to pharmaceutical compositions containing EHNA or an ARADS, all of which are also anticipated in light of applicant's own admissions in the disclosure.

Applicant's arguments filed December 17, 2002 have been fully considered but they are not deemed to be persuasive.

Applicant argues that the noted reference fails to anticipate because it fails to include all of the limitations of the noted claim. Examiner respectfully disagrees noting that the preamble

in claim **15** has no patentable weight whatsoever and that all remaining elements of the claims are anticipated.

Claims **1-4 and 7-14** are rejected under 35 U.S.C. §102(b) as being anticipated by **Erion et al. '432** (PTO-892 ref. C).

Applicant is referred to the '432 patent at column 2, lines 25-32, column 3 at lines 45-57 and at column 4 at lines 8-10 wherein pentostatin and pharmaceutical compositions thereof is disclosed to be an effective treatment for SIRS and to be ADA and AMPDA inhibitors.

Applicant's arguments with respect to claims **1-15** have been considered but are deemed to be moot in view of the new grounds of rejection.

Claims **5 and 6** would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. §112.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 703-872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

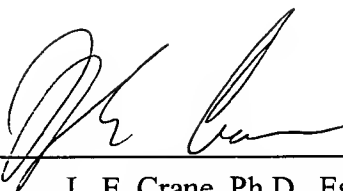
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at **571-272-0661**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

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LECrane:lec
11/18/2004

A handwritten signature in black ink, appearing to read "L. E. Crane", is written over a horizontal line.

L. E. Crane, Ph.D., Esq.
Primary Patent Examiner
Technology Center 1600